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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,518	07/06/2001	Keith D. Allen	R-716	3954

7590 09/09/2002  
DELTAGEN, INC.  
1003 Hamilton Avenue  
Menlo Park, CA 94025

EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/900,518

Applicant(s)

ALLEN ET AL.

Examiner

Celine Qian

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-28 are pending in the application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 17-21, drawn to a CX2 gene target construct, a cell comprising said construct, a transgenic animal comprising a disruption of CX2, a method of making said target construct and a method of making said transgenic animal, classified in class 536, subclass 23.1, class 800, subclass 18 and 21.
- II. Claim 11, drawn to a method of identifying an agent that modulates the expression of a CX2 gene by using a CX2 knockout animal, classified in class 800, subclass 3.
- III. Claim 12, drawn to a method of identifying an agent that modulates the function of a CX2 gene by using a CX2 knockout animal, classified in class 800, subclass 3.
- IV. Claims 13 and 15, drawn to a method of identifying an agent that modulates the expression of a CX2 gene by using a CX2 gene disrupted cell, classified in class 536, subclass 24.5.
- V. Claims 14, 15, drawn to a method of identifying an agent that modulates the function of a CX2 gene by using a CX2 disrupted cell, classified in class 424, subclass 130.1.
- VI. Claims 16 and 27, drawn to an agent that modulates the expression of the CX2 gene, unclassifiable.

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- VII. Claims 16 and 27, drawn to an agent that modulates the function of the CX2 gene, unclassifiable.
- VIII. Claims 22 and 23, drawn to a method of identifying an agent that affects the phenotype of the CX2 knockout transgenic mouse, classified in class 800, subclass 3.
- IX. Claims 24 and 25, drawn to a method of identifying an agent that affects the phenotype of the CX2 disrupted cell, classified in class 435, subclass 325.
- X. Claim 26, drawn to an agent that affects the phenotype of the CX2 knockout mouse, unclassifiable.
- XI. Claim 28, drawn to a method of ameliorating a condition associated with impaired glucose tolerance, classified in class 514, subclass 44.

The inventions are distinct, each from the other for following reasons.

The inventions of Groups I, VI, VII and X are patentably distinct from each other because they are drawn to materially distinct compositions that are not directly related. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. The products of Groups I, VI, VII and IX have different chemical structures, are made by different methods, and can be used in different methods which require different technical considerations and materially different reagents. For example, the transgenic animal non-human animal of Group I can be used as a model of disease while agent of Group IV can be used to modulate CX2 expression. Also, the agents of groups

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VI, VII and X may have different chemical structures from each other, as well as from the targeting construct and transgenic non-human animals of Groups I respectively, and may be used in different methods, which require different technical considerations with respect to modulation of a CX2. Therefore, the inventions of Groups I, VI, VII and X are patentably distinct.

The inventions of Groups II-V, VIII, IX and XI are patentably distinct from each other because the inventions are drawn to methods that require different starting material and modes of operation. Each method constitutes patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. Therefore, the inventions of Groups II-V, VIII and X are patentably distinct.

The compositions of Groups I, VI, VII, X and the methods of Groups II-V, VIII, IX and XI are patentably distinct because the inventions are not directly related. Inventions I and II-V, VIII, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of Group I, for example, the CX2 knockout mouse and CX2 knockout cell, can be used in patentably distinct methods II-V, VIII and IX. Therefore, the inventions of Groups I, II-V, VIII and IX are patentably distinct from each other. The agents of Groups VI, VII and X can be identified by methods other than inventions of Groups II-V and VIII. For example, an agent that modulates CX2 expression can be identified by using a wild type cell expressing CX2. The method of ameliorating a condition associated with glucose intolerance can use an agent that is

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identified by said method. Therefore, the inventions of Groups I, VI, VII, X and Groups II-V, VIII, IX and XI are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
August 26, 2002

  
TERRY MCKELVEY  
PRIMARY EXAMINER